Guidelines for the Treatment of Chlamydia and Gonorrhea Cases and Exposed Sexual Partners by Health Department Staff in Non-Clinical Settings

Developed by the California Department of Health Services' Sexually Transmitted Diseases (STD) Control Branch and the California STD Controllers Association.

Introduction

This document is intended to provide guidance for the practice of field-delivered treatment (FDT) for gonorrhea (GC) or chlamydia (CT). FDT is the delivery of either medication or a prescription for medication by trained health department staff in non-clinical settings, under the oversight of a health department physician.

Executive Summary

These guidelines provide information about patients, procedures, and medications for FDT for CT and GC, recommended to maximize patient and public health benefit while minimizing risk.

- First-choice patient or partner management strategy: an appointment with a clinician at which the patient or partner(s) can receive testing, counseling, and treatment for sexually transmitted disease.
- Appropriate patients: patients diagnosed with CT or GC, or their partners, who have not been treated or have been incompletely or incorrectly treated
- Medication: Recommended drug regimens are:
    - CT: azithromycin (Zithromax*) 1 gram orally once
    - GC: cefpodoxime (Vantin*) 400 mg orally once, PLUS azithromycin (Zithromax*) 1 gram orally once
- Educational materials must accompany medication.
- Patient counseling: abstinence until seven days after treatment and until seven days after partners have been treated
- Re-testing: All patients diagnosed with CT or GC should be re-tested three months after treatment.
- Adverse reactions: It is recommended that a clinician be on call to manage adverse reactions. To report adverse reactions, call 510-620-3400.

Background and Rationale

Appropriate and prompt treatment of persons with STDs is critically important in preventing health complications and interrupting disease transmission in the community. Many STD patients and partners face significant barriers to accessing needed clinical services; thus may remain untreated for their infections. Providing medication or a prescription for medication in non-clinical settings offers a means to overcome some of these barriers and ensure more timely treatment.

The purpose of these guidelines is to support local health departments in California to take action to ensure that STD patients and partners receive appropriate and timely treatment. Current regulations outlined in California's health and safety code specify that ensuring STD treatment is the responsibility of local health jurisdictions, and, by analogy, support the safety of delivering medication for GC and CT without examination if exposure is documented. Health officers may take necessary reasonable measures to prevent the spread of communicable diseases, including STDs (for supporting legal code, see Appendix A).

These guidelines focus on CT and GC because (1) these infections are of public health importance and are reportable, (2) treatment can be accomplished with oral medication, and (3) the benefits of treatment outweigh the risks, particularly in patients who would not otherwise receive treatment.

STD Controllers are encouraged to collaborate with their local health officers to determine appropriate control measures.

Guidance for FDT

An appointment with a clinician at which the patient or partner(s) can receive testing and care for all STDs and HIV is preferred management of patients with a diagnosis of chlamydia or gonorrhea. Field-delivered therapy is a tool for ensuring treatment which should only be used when a clinic appointment can not be made or would not be attended in a timely manner. Clinical referrals and educational materials must be provided to the patient or partner along with the field-delivered therapy.

Another way to manage treatment for partners who cannot or will not attend a clinic appointment is patient-delivered partner therapy (PDPT); guidelines for PDPT are available here: *http://www.dhs.ca.gov/ps/dcdc/STD/docs/PDT_GUIDELINES_19.pdf .*

Definition: Field-delivered treatment is defined as:

The delivery of oral medication or a prescription for medication

- For gonorrhea or chlamydia
- By trained health department field staff under the supervision of a health department clinician
- To
  - Patients diagnosed with chlamydia or gonorrhea who
    - Were diagnosed in a health department clinic and did not return for treatment
    - Were diagnosed in a private or other non-health department clinic and did not return for treatment
    - Were diagnosed and treated but did not follow the treatment regimen or vomited soon after treatment and did not visit a clinician for re-treatment.

- Partners of patients diagnosed with chlamydia or gonorrhea in a health department or private or other non-health department clinic if the field staff person believes the partner will be unable to seek evaluation and treatment promptly. For these partners, protocols for patient-delivered partner therapy can also be followed.

Appropriateness: Field-delivered treatment is an appropriate option for:

- Patients diagnosed with chlamydia or gonorrhea who are unable or unlikely to seek treatment in a timely fashion
- Partner(s) of a patient diagnosed with chlamydia or gonorrhea have been sexually exposed to the patient within the period of infection and are unable or unlikely to seek care and treatment in a timely fashion
  Potential coinfection (with syphilis, HIV, or other STDs) is addressed in appendix B

Means:

Notification of the diagnosing clinician: Ideally, the diagnosing clinician will be notified that the health department is initiating FDT. If the request for follow-up has come from the clinician, or for ongoing referrals for health department follow-up, e.g. routine follow-up for cases diagnosed but not treated in jails, there is no further need to contact providers.

The encounter should include:

- Education of the patient regarding disease and treatment
- Risk-reduction and safer sex counseling
- Assessment of contraindications (see below)
- Documented consent to treatment (contact and patient interview materials can be found in appendices C and D.)

Recommended field-delivered treatment:

- For PATIENTS diagnosed with chlamydia,
  - oral medication for chlamydia (Azithromycin 1 g)
  - or a prescription for this medication

- For PATIENTS diagnosed with gonorrhea,
  - oral medication for gonorrhea (cefpodoxime 400 mg)
  - plus, if not tested for chlamydia using a sensitive nucleic acid amplification test (NAAT), oral medication for chlamydia (Azithromycin 1 g)
  - or prescriptions for these medications

- For PARTNERS of patients diagnosed with CT oral medication for chlamydia
  - Azithromycin 1 g

    - or a prescription for this medication

- For PARTNERS of patients diagnosed with gonorrhea,
    - oral medication for gonorrhea (cefpodoxime 400 mg)
    - plus oral medication for chlamydia (Azithromycin 1 g)
    - or prescriptions for these medications

- Other treatments may be authorized locally

Contraindications to field-delivered treatment:

- Females:
    - Lower abdominal pain
    - Pain with sex
    - Fever
    - Indication of allergy to penicillin and/or cephalosporins, including cefpodoxime, for patients in need of treatment for gonorrhea (allergy risk and other drug information is detailed in appendix F)
    - Indication of allergy to macrolides, including azithromycin, for patients in need of treatment for chlamydia or co-treatment for gonorrhea
    - Serious illness such as heart, liver, or kidney disease
    - Field-delivered treatment is generally not appropriate for pregnant women; these women should be in prenatal care and treatment should be provided by the prenatal care provider. If the patient is unable or unwilling to access prenatal care, the case should be reviewed by a health department physician before treatment.

- Males:
    - Pain or swelling in testicles
    - Fever
    - Indication of allergy to penicillin and/or cephalosporins, including cefpodoxime for patients in need of treatment for gonorrhea.
    - Indication of allergy to macrolides, including azithromycin, for patients in need of treatment for chlamydia or co-treatment for gonorrhea
    - Serious illness such as heart, liver, or kidney disease

National guidance can be found in appendix E, other questions and answers in appendix G, and the bibliography in appendix H.

Appendices

A. California Health and Safety Code Language

B. Co-infection

C. Contact procedures

D. Patient interview materials guidance, including sample consent form

E. National guidance

F. Allergy risk and other drug information

G. Questions and Answers

H. Bibliography

Appendix A: California Health and Safety Code Language

Part 1. Administration of Communicable Disease Prevention and Control
Chapter 3. Functions and Duties of Local Health Officers
§120175. Prevention of spread of disease
Each health officer knowing or having reason to believe that any case of the diseases made reportable by regulation of the department, or any other contagious, infectious or communicable disease exists, or has recently existed, within the territory under his or her jurisdiction, shall take measures as may be necessary to prevent the spread of the disease or occurrence of additional cases.

Part 3. Sexually Transmitted Disease
Chapter 1. Prevention and Control
§120530 Furnishing treatment for venereal disease cases
The department may furnish treatment for a case or for a group of cases in rural counties or cities upon the recommendations of the local health officer if adequate facilities for the treatment are not available in the county or city.

§120575 Local health officers; investigation and preventive measures
It is the duty of the local health officers to use every available means to ascertain the existence of cases of infectious venereal diseases within their respective jurisdictions, to investigate all cases that are not, or probably are not, subject to proper control measures approved by the board, to ascertain so far as possible all sources of infection, and to take all measures reasonably necessary to prevent the transmission of infection.

Appendix B: Co-infection

Every effort should be made to provide rapid HIV and syphilis testing to patients and partners who have not been tested for these infections.

It is possible that a partner eligible for field-delivered therapy (FDT) may have an undiagnosed sexually transmitted disease (STD). Research evaluating the risk of missed infections for patient delivered partner therapy (PDPT) (as reviewed in Golden, *Clin Infect Dis 2005;* 41:630-633) suggests that the probability of additional (other than gonorrhea (GC) and/or chlamydia (CT)) co-infections in heterosexual partners of patients infected with CT or GC is small, although not nonexistent.

These data suggest that the benefits of FDT outweigh the risk of potential missed co-infection in these populations. However, 20 percent of partners of STD clinic attendees infected with GC were also infected with trichomonas in one study using nucleic acid amplification testing to assess trichomonas infection (Kahn et al., *Sex Transm Dis* 2005, Apr; 32 (4):260-264). Another study reported an HIV infection rate of six percent among partners of men who have sex with men (MSM) who were not diagnosed with HIV (Stekler et al., *Clin Infect Dis 2003;* 40:787-793). In particular, in populations where HIV prevalence is relatively high (e.g., sexually transmitted infections (STI)-infected attendees of some STD clinics), the potential to miss HIV co-infection may warrant increased efforts to have the patient/partner seen by a clinician.

Decisions about the appropriateness of FDT should be made on the basis of local epidemiology.

Appendix C: Contact procedures

- Health department staff will:
  - pre-arrange a time/place to meet the patient or partner;
  - confirm identity of the patient or partner;
  - assess treatment status to determine whether treatment for the infection has been received by the patient/partner;
  - educate the patient/partner about sexually transmitted diseases (STD) risk, condoms, the diagnosed disease, and possible co-infections;
  - determine whether the patient/partner is unable or unlikely to attend a health department clinic or an appointment with another clinician. Every effort should be made to refer the patient/partner to his/her healthcare provider or a health department clinician for treatment.

- If the patient/partner is unable or unlikely to see a clinician, health department staff should proceed to:
  - assess contraindications;
  - educate patient/partner about:
    - medication, potential reactions, and how to seek help; and
    - abstinence during the period of drug action;
  - obtain informed consent from the patient/partner;
  - deliver medication or prescription from Health Officer or STD Controller;
  - if medication delivered and observed, monitor the patient for adverse reactions;
    - It is recommended that a clinician be on call to accept patients with adverse reactions.
  - recommend re-testing in three months;
  - document encounter, including lot number and expiration date of the medication administered.

- Health department staff will educate patient/partner about the necessity to inform partners and bring them for treatment:
  - Staff may provide partner packs for patient-delivered partner therapy if it is assessed that the partner(s) is/are unlikely to seek timely treatment.

Appendix D: Patient materials

I. Patient education materials

Patient education materials should include written information about the patient's infection and treatment, as well as counseling regarding partner evaluation and treatment, safer sex and risk reduction, and the importance of follow-up at a medical clinic.

These materials should also include information about adverse reactions to treatment and contact information in case of adverse reaction or general questions.

Sample educational materials will be made available by the California Department of Health Services, STD Control Branch.

Appendix D, cont'd.

II. Sample patient consent form

Field-Delivered Treatment Record

Client name_____ DOB __/__/____Test result date __/__/____
Client gender: F M FTM MTF Diagnosis: CT GC Contact to CT Contact to GC
Testing site_____
Medication ordered by _____ Date ordered__/__/____
Medication lot number _____ Expiration date__/__/____
Treatment delivered by _____ Date__/__/____ DOT: Y N

Explain the following items to client and check to indicate completion:

- Clinical importance of chlamydia (CT) infection, including symptoms and complications; supply patient with written materials.
- Risk reduction and safer sex
- Indicate clinic referral here: _____.
  If patient is unable/unwilling to attend clinic, proceed with checklist.
- Does the client currently have any of the following symptoms?
  - Females:
    - lower abdominal pain
    - pain with sex
    - vomiting
    - fever
    - indication of allergy to:
      - azithromycin or related compounds such as erythromycin
      - cefpodoxime or related compounds such as penicillin
    - serious illness, such as heart, liver, or kidney disease
    - If pregnant, the case should be reviewed by a health department physician.
  - Males:
    - pain or swelling in testicles
    - fever
    - indication of allergy to azithromycin/cefpodoxime or related compounds
    - serious illness, such as heart, liver, or kidney disease

  If yes, DO NOT TREAT. Refer to clinic.

- Review written materials about treatment, including abstinence for seven days.
- Provide treatment (indicate as appropriate).

I give my consent to receive treatment for chlamydia/gonorrhea. The information provided about my current health status is correct to the best of my knowledge.

_____ _____
Patient signature Date Field staff signature Date

Appendix E: National guidance

The Centers for Disease Control and Prevention (CDC) Sexually Transmitted Disease (STD) Prevention Program has released a Dear Colleague letter: (*http://www.cdc.gov/std/DearColleagueEPT5-10-05.pdf)* and a white paper: (*http://www.cdc.gov/std/treatment/EPTFinalReport2006.pdf)*, discussing the use of expedited partner therapy (EPT), or delivering medication to the partner of a case-patient via the case-patient, without a visit to a doctor by the partner.

While these documents do not address field-delivered treatment (FDT) specifically, the practice is analogous to FDT to partners or to case-patients seen by non-health department clinicians, in that there is no clinical evaluation by the provider administering the medication. CDC has endorsed the safety of EPT; FDT by a trained health department staff person is likely to be as safe as or safer than this CDC-endorsed practice.

Appendix F*:* Allergy risk and other drug information

One study found a rate of immunoglobulin E (IgE)-associated cross-reactivity between penicillin and cephalosporins of ten percent (previously, best estimates suggested three percent to seven percent); however, IgE-associated reactivity does not invariably lead to symptoms of allergy. The incidence of allergic reactions to cephalosporins has been calculated to be one percent to three percent, with more penicillin cross-reactivity occurring with first-generation than with second- or third-generation cephalosporins such as cefpodoxime (Pichichero M, *Pediatrics* 2005; 115:1048-1057).

A very large study found that, although patients who had allergic-like events after taking penicillin were more likely to have allergic-like events after a subsequent prescription of cefpodoxime than were those who did not have a reaction to the initial penicillin, patients were as likely to have allergic-like events if the subsequent prescription was a sulfonamide as they were if it were cefpodoxime. This study found an absolute risk of anaphylaxis after cephalosporin treatment of less than 0.001 percent (Apter AJ et al., *Am J Med* 2006; 119:354.e11-354.e20). Therefore, the risk of anaphylaxis due to field-delivered treatment (FDT) with cefpodoxime is low.

Patients with confirmed penicillin or cephalosporin allergy should be assessed in the clinic setting rather than offered FDT.

Current information indicates that "allergy" due to azithromycin is rare to nonexistent.

Appendix G: Questions and Answers

Safety of medication: The medications recommended for field-delivered treatment (FDT) for chlamydia (CT) (azithromycin) or gonorrhea (GC) (cefpodoxime) are safe and have few side effects.

Treatment of and purchase of medication for patients diagnosed by non-health department clinicians: Untreated cases of CT or GC are a public health concern. Therefore, it is appropriate for treatment for these cases to be delivered by health department personnel, and appropriate for the medication delivered by health departments to be purchased under public health pricing.

Overuse/misuse of antibiotics: As FDT is recorded at the clinic and is delivered by trained health department personnel, the risk for overuse or misuse of antibiotics is minimal and less than that for partner-delivered treatment.

Liability issues: FDT of persons diagnosed with CT/GC or partners of persons diagnosed with CT/GC is analogous to patient-delivered partner therapy (PDPT), with the additional safety that FDT is delivered by trained health department personnel, including registered nurses, public health nurses, disease investigators, or public health investigators. FDT is a low-risk procedure and is an option for high-risk, uninsured patients or partners with no access to timely health care. This is an option in the continuum of partner treatment management, and, if public health staff are available, FDT should be used before PDPT, which is the option of last resort to get partners treated.

Appendix H: Bibliography

Few published studies address field-delivered treatment directly. Studies and editorials addressing this topic are listed here.

1. Auerswald CL, Sugano E, Ellen JM, Klausner JD. Street-based STD testing and treatment of homeless youth are feasible, acceptable, and effective. *J Adolesc Health* 2006; 38(3):208-212.

2. Golden MR. Expedited partner therapy for sexually transmitted diseases. *Clin Infect Dis* 2005; 41(5):630-633.

3. Steiner KC, Davila V, Kent CK, et al. Field-delivered therapy increases treatment for chlamydia and GC. *Am J Public Health* 2003; 93(6):882-884.

Studies addressing the risk of co-infection:

1. Khan A, Fortenberry JD, Juliar BE, et al. The prevalence of chlamydia, GC, and trichomonas in sexual partnerships: implications for partner notification and treatment. *Sex Transm Dis* 2005; 32(4):260-264.

2. Stekler J, Bachmann L, Brotman RM, et al. Concurrent sexually transmitted infections (STIs) in sex partners of patients with selected STIs: implications for patient-delivered partner therapy. *Clin Infect Dis* 2005; 40(6):787-93.

Studies addressing allergy risk:

1. Pichichero M. A review of evidence supporting the American Academy of Pediatrics Recommendation for prescribing cephalosporin antibiotics for penicillin-allergic patients. *Pediatrics* 2005; 115:1048-1057.

2. Apter AJ, Kinman JL, Bilker WB, et al. Is there cross-reactivity between penicillins and cephalosporins? *Am J Med* 2006; 119:354.e11-354.e20.

Guidelines for Patient-Delivered Partner Therapy:

California Department of Health Services, STD Control Branch. Patient-Delivered Therapy of Antibiotics for *Chlamydia trachomatis:* Guidance for Medical Providers in California. 2001; *www.dhs.ca.gov/ps/dcdc/STD/docs/PDT_GUIDELINES_19.pdf*